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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,833	12/17/2001	David John Heal	2475/002628	1200

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WASHINGTON, DC 20036

EXAMINER

HENLEY III, RAYMOND J

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 04/11/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/009,833

Applicant(s)
David John Heal

Examiner
Ray Henley

Art Unit
1614



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

Art Unit: 1614

CLAIMS 1-8 ARE PRESENTED FOR EXAMINATION

Claim Rejection - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 7 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. See, for example, *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966) respecting the impropriety of claims reciting "Use of...". Accordingly, this claim has not been further treated on the merits.

Claim Rejection - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4-6 recites the limitation "compound of formula I" and "compound of formula II. There is insufficient antecedent basis for this limitation in the claim. Insofar as the metes and

Art Unit: 1614

bounds of the subject matter for which applicant seeks patent protection is so unclear, further examination on the merits is precluded regarding claims 4-6.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buttle (Exp. Opin. Invest. Drugs (1996), 5(12):1583-1587) and Wilding (BMJ Volume 315, 18 October 1997, pp 997-1000).

Buttle and Wilding teach that sibutramine and orlistat are drugs which are effective for the treatment of obesity. See Buttle at page 1584, column 2, last paragraph - page 1586, column 2, last line before the heading "Concerns Over Abuse Potential" and Wilding at page 999, column 9, the entire section under the heading "Future drug targets".

The differences between the above and applicant's claimed subject matter lie in that the references fail to highlight:

- (1) the treatment of co-morbid conditions associated with obesity; and
- (2) a specific composition or method comprising both sibutramine and orlistat.

Art Unit: 1614

However, to the skilled artisan, applicant's claimed subject matter would have been obvious because:

(1) the references teach the treatment of obesity in general and as such, it is believed that the skilled artisan would have readily recognized that pathophysiological sequela of obesity would also be effectively treated; and

(2) Wilding at page 1000, column 1, lines 8-11 teach "[t]here are many possible new therapeutic targets, and combinations of drugs with different modes of action may be required, as is currently the case with hypertension". Insofar as sibutramine and orlistat possess differing modes of action, it is believed that a combination of the two drugs is thus reasonably suggested.

Also, it has been held that it is considered prima facie obvious to have combined two or more ingredients each of which was known to be useful for the same purpose in order to form a third composition that is useful for the very same purpose. The idea for combining them flows logically from their have been used separately. See In re Kerkhoven 205 U.S.P.Q. 1069 (CCPA 1980) and the cases cited therein. The skilled artisan would have been motivated to combine such ingredients in order to achieve at least additive results and to provide the individual being treated with the most convenient, effective therapy possible.

Accordingly, for the above reasons, the claims are deemed to be properly rejected and none of the claims are allowed.

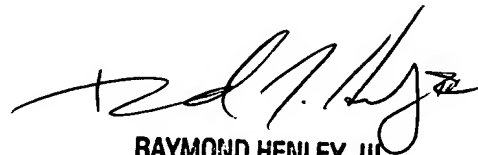
The references cited on the attached form PTO-892 were included in the papers filed with the present application. Accordingly, copies of such references have not been provided.

Application/Control Number: 10/009,833

Page 5

Art Unit: 1614

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Henley whose telephone number is (703) 308-4652.

A handwritten signature in black ink, appearing to read 'Ray Henley, III', is positioned above the printed name.

**RAYMOND HENLEY, III
PRIMARY EXAMINER
GROUP 1200**

Henley; rjh
April 8, 2002